

Appln No. 10/715,684  
Reply to Office action of October 13, 2006

**Amendments to the Drawings:**

The attached sheets of drawings replaces Figs. 1 to 3 as originally filed.

Attachment:            Replacement Sheets

**REMARKS/ARGUMENTS**

Claims 1 to 37 were previously pending in this application. With this amendment Applicant has cancelled claims 1 to 16, amended claims 17, 20, 22, 32 and 36, and has added new claims 38 and 39. No new matter has been added with these amendments.

**Objections to the Drawings**

The Examiner objected to FIG. 3 based on the presence of a duplicate reference numeral "68". Applicant has reviewed the drawing in question and can find no such duplicate reference numeral. However, because the original drawings were informal, Applicant is submitting a new set of formal drawings herewith.

**Claim Objections**

The Examiner objected to the text of claim 12 based on a typographical error. Applicant has cancelled this claim thereby obviating this objection.

**Rejections Under 35 U.S.C. §112**

The Examiner rejected claims 17 to 35 under 35 U.S.C. §112, second paragraph as indefinite based on the passage "the angle between the shaft and the handle of the axis." Applicant has amended this passage to recite "the angel between the shaft and the axis of the handle," as set forth in claim 1 of the application, thereby obviating this rejection.

**Rejections Under 35 U.S.C. §102**

**Williams Reference**

The Examiner rejected claims 1, 3, 4, and 11 under 35 U.S.C. §102(b) as being anticipated by Williams (USPN 4, 049,000). Applicant has cancelled claims 1 to 16, thereby obviating this rejection

Suddaby Reference

The Examiner also rejected claims 1, 3, 4, 7, 8, 12, 14, 16-19, 21, 23, 24, 27, 28, 32 and 34 under 35 U.S.C. §102(e) as being anticipated by Suddaby (US Pub. No. 2004/0143164). Applicant respectfully traverses this rejection.

The newly amended claims have been revised to more clearly recite one of the key features of the current invention, namely the ability to controllably adjust and fix the angle of the instrument. Specifically, amended claim 17, upon which the remaining rejected claims all depend recites:

a nerve root retractor/sucker shaft having a proximal open end and a distal open end and defining a central passage therebetween, wherein the proximal end of the shaft is connected to the distal end of the handle, and wherein *the angle between the shaft and the axis of the handle may be controllably and fixedly varied along at least one axis*;

(Claim 1, italics added for emphasis.)

The specification repeatedly emphasizes the importance of the device's ability to be fixedly adjusted both in the summary of the invention which recites among other sections:

- can be manually bent to conform to a desired shape, by the operating surgeon at his wish (Specification, page 3, lines 15 to 18.);
- . . . simultaneously prevent further polyaxial motion of the shaft, thereby fixing the angular position of the shaft in relation to the handle (Specification, page 10, lines 15 to 21.)

In the Office action the Examiner asserts that the Suddaby patent also provides the ability to vary the angle between the handle and the shaft because "the shaft is flexible." (Office action, page 3, last paragraph.) However, in contrast to the current invention, the Suddaby invention does not provide the ability to either "controllably" or "fixedly" adjust the angle of the device, instead Suddaby merely provides a shaft that will flex when placed under sufficient pressure to prevent damage to the underlying tissue. Specifically, Suddaby recites"

. . . I prefer the probe to be substantially flexible. This is done by making the probe of a low-modulus material such as a plastic or elastomeric material, and

then selecting the dimensions of the probe shaft so that it will flex substantially under a tip load of about 75 grams or more. If the surgeon displaces the tool too much, creating a danger of exceeding this limit, the shaft flexes and gives way gradually and in a controlled fashion to prevent over-retraction. (Suddaby, page 1, 2nd col., paragraph [0021].)

In short, Suddaby only contemplates a probe shaft that is flexible under emergency stress, and nowhere does Suddaby ever contemplate forming a shaft that may be fixed into a particular conformation by the surgeon.

In light of these deficiencies, Applicant submits that the Suddaby reference cannot be said to anticipate claims 1, 3, 4, 7, 8, 12, 14, 16-19, 21, 23, 24, 27, 28, 32 and 34 of the current application.

#### **Rejections Under 35 U.S.C. §103**

##### Williams & Leffler

The Examiner rejected claims 2, 5, 6, and 13 under 35 U.S.C. §103(a) as being unpatentable over Williams in view of Leffler (USPN 3,516,160). Applicants have cancelled all the rejected claims, thereby obviating this rejection.

##### Williams

The Examiner also rejected claims 8 and 9 under 35 U.S.C. §103(a) as being unpatentable over Williams in view of the level of ordinary skill in the art. Applicants have cancelled all the rejected claims, thereby obviating this rejection.

##### Suddaby & Folko

The Examiner rejected claim 20 under 35 U.S.C. §103(a) as being unpatentable over Suddaby in view of Folko et al. (USPN 5,743,736). Applicants respectfully traverse this rejection.

As discussed above, the current invention is directed to a nerve root retractor having a shaft that has an angled region that can be controllably and fixedly adjusted by the surgeon. In one embodiment this adjustability is provided by a ball and socket fitting. Although Suddaby does not teach any such fitting, the Examiner cites the Folko et al. reference for this teaching.

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However, even though the Folko reference does describe a device having a multiplicity of ball and socket joints, none of these joints can be "fixed" into place as required by the claims of the current invention. Specifically, in describing the joints, Folko et al. write,

By means of the connections between the separate parts 10, 12, and 14 it is additionally possible by applying a certain minimum force to form the saliva ejector 1 to some desired bent shape . . . (Folko et al., col. 3, lines 11 to 15; see also Abstract.

In short, there is no means provided for locking the ball and socket joints to allow for the fixation of the desired shape as required by the claims of the current invention. Nor is there any contemplation of such a means as the device described in Folko et al. is specifically designed to be "disposable" and simple to dispose of and destroy after use.

Accordingly, Applicant submits that one of ordinary skill in the art having been aware of both the Suddaby and Folko et al. references would have had no motivation to form the apparatus of the current invention.

Suddaby & Leffler

The Examiner rejected claims 22, 25, 26, 34 and 35 under 35 U.S.C. §103(a) as being unpatentable over Suddaby in view of Leffler. Applicants respectfully traverse this rejection.

The Examiner cites Leffler as providing a disclosure of multiple vents and a detachable shaft. However, as previously discussed, Suddaby also fails to disclose a shaft that has an angled region that can be controllably and fixedly adjusted by the surgeon. The Leffler patent does not address this deficiency. Accordingly, Applicant submits that one of ordinary skill in the art having been aware of both the Suddaby and Leffler reference would have had no motivation to form the apparatus of the current invention.

Suddaby

The Examiner also rejected claims 29 to 31 under 35 U.S.C. §103(a) as being unpatentable over Suddaby in view of the level of ordinary skill in the art. Again, for the reasons stated above, Applicants respectfully traverse this rejection. Suddaby never contemplates forming a shaft that may be fixed into a particular conformation by the surgeon, nor does the Examiner ever contend that it would have been an obvious design choice to form the shafts in

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such a way as to allow them to be fixedly adjustable. Accordingly, Applicant submits that one of ordinary skill in the art having been aware of the Suddaby reference would have had no motivation to form the apparatus of the current invention.

Williams & Cise

The Examiner also rejected claims 36 and 37 under 35 U.S.C. §103(a) as being unpatentable over Williams in view of Cise et al. (USPN 6,129,547). Applicant respectfully traverses this rejection.

Applicant has amended claim 36, upon which claim 37 depends to require an angularly adjustably and fixable shaft. Neither Williams nor Cise et al. provide any disclosure of such an angularly adjustable instrument. Accordingly, Applicant submits that one of ordinary skill in the art having been aware of both the Williams and Cise et al. references would have had no motivation to form the apparatus of the current invention.

**Conclusion**

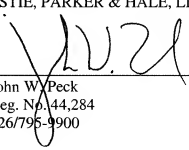
In view of the foregoing amendments and remarks, claims 17 to 39 are in condition for allowance and, accordingly, a timely indication thereof is respectfully requested. If any questions remain regarding the allowability of the application, Applicant would appreciate if the Examiner would advise the undersigned by telephone.

The Commissioner is hereby authorized to charge any fees under 37 CFR 1.16 and 1.17 which may be required by this paper to Deposit Account No. 03-1728. Please show our docket number with any charge or credit to our Deposit Account.

Respectfully submitted,

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